

Appl. No. 10/027,263
Amdt. dated November 16, 2004
Reply to Office Action of June 29, 2004

REMARKS

Claims 1-56 are pending in the instant application. In the Office Action mailed June 29, 2004, the Examiner rejects claims 1-9, 12, 16, 20-32, 34-36, 38-40, 43-45, 47, 49-51, and 53-55. Claims 10, 11, 13-15, 17-19, 33, 37, 41, 42, 46, 48, and 52 are withdrawn from consideration. Claims 2, 42-45, and 51 are canceled. New claim 56 is added.

By virtue of the amendments to the claims presented above, independent claims 1, 50, and 54 are amended. New claim 56 is presented. No new subject matter is added. Based on the amendments and remarks made herein, Applicants respectfully request that the rejections be withdrawn and that the application be passed to allowance.

1. Remarks on Paragraphs 2-3 of the Office Action mailed on June 29, 2004: Rejection of Claims 1-4, 7, 12, 22, 26, 31, 32, 34, 42-45, 50, 51, 54, and 55 Under 35 U.S.C. §102(b)

In the Office Action mailed June 29, 2004, the Examiner rejects claims 1-4, 7, 12, 22, 26, 31, 32, 34, 42-45, 50, 51, 54, and 55 as being unpatentable under 35 U.S.C. §102(b) over Australian Patent Application No. AU 199941153 to Lucas (hereinafter "the Lucas application").

With respect to claims 1, 3, 31, 32, 42, 43, 50, and 51, the Examiner believes the Lucas application discloses a tampon and method for producing a tampon comprising a fluid-absorbent body and a therapeutic agent located within an application region of the tampon and the therapeutic agent is a botanical (page 2, lines 1-3; page 3, lines 18-23 and Figures 1 and 2).

Claim 1 as amended is directed to a tampon adapted to deliver a therapeutic agent, the tampon including absorbent material and a formulation including a therapeutic agent, wherein the therapeutic agent is a botanical, wherein the tampon has an outer layer, and wherein the outer layer includes a therapeutically sufficient amount of the botanical. As described in the Lucas application at page 3, lines 20-22, the "herbal preparation shall be evenly spread in a thin layer from the centre to the periphery of the herbal tampon following the concentric layers." As further illustrated in Figs. 1 and 2, the Lucas application discloses what might be analogized as a jelly roll model, wherein the layer of herbal preparation extends in a spiral manner from the center of the tampon to the periphery of the tampon. As stated in the Lucas application at page 3, lines 24-25, "Such layering of the herbal preparations shall give a slow release of the active constituents of the herbal preparations." Contrarily, the Applicants' claimed invention includes a therapeutically sufficient amount of botanical in an outer layer, and does so for at least the reason of enabling a quicker and more complete release of the botanical. In the device of the Lucas application, release of the active constituents competes with the in-rush of menstrual fluids. As a result, much of the active constituents will remain within the tampon. In addition, tampons are typically used for a

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limited time within the body; consequently, the "slow release" of the Lucas application will preclude complete release of its active constituents.

Claim 3 as amended is directed to the tampon of claim 1, wherein the outer layer is a cover. The Lucas application does not disclose its tampon as having a cover. In fact, the Lucas application describes its tampon as being of one material (see Abstract, lines 4-5 "the tampon material").

Claim 31 is directed to the tampon of claim 1, further including a pledget, wherein the formulation including a therapeutic agent is applied to the pledget. Claim 31 is a dependent claim that depends from an allowable independent claim, and is thus allowable itself for the reasons stated above with respect to claim 1.

Claim 32 is directed to the tampon of claim 1, wherein the tampon includes a surface, and wherein the formulation including a therapeutic agent is applied to the surface. As described above, the Lucas application discloses applying the herbal preparation to tampon material, which is then formed into a tampon. The herbal preparation is thereby distributed throughout the tampon. The Lucas application does not disclose applying a formulation including a therapeutic agent to a surface of the tampon.

Claim 34 is directed to tampon of claim 1, wherein the tampon includes a body constructed from a material, and wherein the formulation including a therapeutic agent is applied to the material before the body is constructed. Claim 34 is a dependent claim that depends from an allowable independent claim, and is thus allowable itself for the reasons stated above with respect to claim 1.

Claim 50 as amended is directed to a device for delivering a therapeutic agent, the device including a tampon body including absorbent material, wherein the tampon body has a surface; and means for carrying a formulation including a therapeutic agent within the body, wherein the therapeutic agent is a botanical, and wherein the carrying means is substantially positioned adjacent the surface. As discussed with respect to claim 1, and as described in the Lucas application at page 3, lines 20-22, the "herbal preparation shall be evenly spread in a thin layer from the centre to the periphery of the herbal tampon following the concentric layers." As further illustrated in Figs. 1 and 2, the Lucas application discloses what might be analogized as a jelly roll model, wherein the layer of herbal preparation extends in a spiral manner from the center of the tampon to the periphery of the tampon. As stated in the Lucas application at page 3, lines 24-25, "Such layering of the herbal preparations shall give a slow release of the active constituents of the herbal preparations." Contrarily, the Applicants' claimed invention includes a means for carrying a formulation including a therapeutic agent within the body, wherein the carrying means is

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substantially positioned adjacent the surface. The Applicants' claimed invention does so for at least the reason of enabling a quicker and more complete release of the botanical. In the device of the Lucas application, release of the active constituents competes with the in-rush of menstrual fluids. As a result, much of the active constituents will remain within the tampon. In addition, tampons are typically used for a limited time within the body; consequently, the "slow release" of the Lucas application will preclude complete release of its active constituents.

With respect to claim 21, the Examiner believes the Lucas application discloses a therapeutic agent capable of treating dysmenorrhea (page 4, lines 7-10). Claim 21 is directed to the tampon of claim 1, wherein the therapeutic agent is an emulsion. The Applicants respectfully ask the Examiner to clarify the relevance of this argument. The Lucas application does not disclose a therapeutic agent as an emulsion.

With respect to claim 7, the Examiner believes the Lucas application discloses a therapeutic agent applied to the surface of a tampon body (page 3, lines 18-23 and Figures 1 and 2). Claim 7 is directed to the tampon of claim 6, wherein the botanical is coated on the fibers. In addition to the discussion above with respect to claim 1 and the Lucas application not disclosing a therapeutic agent applied to the surface of a tampon body, the Lucas application does not disclose the use of fibers, and thus cannot disclose a botanical coated on fibers.

With respect to claim 4, the Examiner believes the cover of the Lucas application is inherently liquid-permeable. Claim 4 is directed to the tampon of claim 3, wherein the cover is liquid-permeable. Claim 4 is a dependent claim that depends from an allowable independent claim, and is thus allowable itself for the reasons stated above with respect to claim 1.

With respect to claim 12, the Examiner believes the Lucas application discloses *rehmannia glutinosa* may be used instead of licorice (page 7, lines 1-4). Claim 12 as amended is directed to the tampon of claim 1, wherein the botanical is selected from the group consisting of: *Agnus castus*, aloe vera, comfrey, calendula, dong quai, black cohosh, chamomile, evening primrose, *Hypericum perforatum*, black currant seed oil, St. John's wort, tea extracts, lemon balm, capsicum, rosemary, *Areca catechu*, mung bean, borage seed oil, witch hazel, fenugreek, lavender, and soy. The Lucas application does not disclose any of the botanicals included in claim 12.

With respect to claims 22 and 26, the Examiner believes the Lucas application discloses a therapeutic agent as a powder, which is also a solid (page 2, lines 12-14). Claim 22 is directed to the tampon of claim 1, wherein the therapeutic agent is a powder. Claim 26 is directed to the tampon of claim 1, wherein the therapeutic agent is substantially a solid. Claims 22 and 26 are

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dependent claims that depend from an allowable independent claim, and are thus allowable themselves for the reasons stated above with respect to claim 1.

With respect to claim 34, the Examiner believes the Lucas application discloses a therapeutic agent applied to the surface of a tampon body. Claim 34 is directed to the tampon of claim 1, wherein the tampon includes a body constructed from a material, and wherein the formulation including a therapeutic agent is applied to the material before the body is constructed. Claim 34 is a dependent claim that depends from an allowable independent claim, and is thus allowable itself for the reasons stated above with respect to claim 1.

With respect to claim 54, the Examiner believes in part that the Lucas application discloses exposing the epithelium to a formulation including a therapeutic agent residing on a tampon. Claim 54 as amended is directed to a method of treating a woman via the vaginal epithelium, the method including exposing the epithelium to a formulation including a therapeutic agent residing on a tampon, the therapeutic agent including a botanical, wherein the tampon has an outer layer, wherein the outer layer includes a therapeutically sufficient amount of the botanical, and wherein the botanical is selected from the group consisting of *Agnus castus*, aloe vera, comfrey, calendula, black cohosh, chamomile, evening primrose, *Hypericum perforatum*, black currant seed oil, St. John's wort, tea extracts, lemon balm, capsicum, rosemary, *Areca catechu*, mung bean, borage seed oil, witch hazel, fenugreek, lavender, soy, heath, cranberries, blueberries, azaleas, red onion skin, short red bell peppers, long red bell peppers, beet root extract, capsanthin, whortleberry, lingonberry, chokeberry, sweet rowan, rowanberry, seabuckthrouberry, crowberry, strawberries, and gooseberries. First, as discussed with respect to claim 1, and as described in the Lucas application at page 3, lines 20-22, the "herbal preparation shall be evenly spread in a thin layer from the centre to the periphery of the herbal tampon following the concentric layers." As further illustrated in Figs. 1 and 2, the Lucas application discloses what might be analogized as a jelly roll model, wherein the layer of herbal preparation extends in a spiral manner from the center of the tampon to the periphery of the tampon. As stated in the Lucas application at page 3, lines 24-25, "Such layering of the herbal preparations shall give a slow release of the active constituents of the herbal preparations." Contrarily, the Applicants' claimed invention includes a tampon that has an outer layer, wherein the outer layer includes a therapeutically sufficient amount of the botanical. The Applicants' claimed invention does so for at least the reason of enabling a quicker and more complete release of the botanical. In the device of the Lucas application, release of the active constituents competes with the in-rush of menstrual fluids. As a result, much of the active constituents will remain within the tampon. In addition, tampons are typically used for a limited time within the body; consequently, the "slow release" of the Lucas application will preclude complete

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release of its active constituents. Second, the Lucas application does not disclose any of the botanicals included in claim 54.

With respect to claim 55, the Examiner believes the Lucas application discloses a therapeutic agent that is a combination of a botanical and a beneficial agent from the claimed types of beneficial agents (page 3, lines 4-17). Claim 55 is directed to the method of claim 54, wherein the exposing act includes a therapeutic agent that is a combination of a botanical and a beneficial agent selected from the group consisting of: vitamins, calcium, magnesium, hormones, analgesics, prostaglandin inhibitors, prostaglandin synthetase inhibitors, leukotriene receptor antagonists, essential fatty acids, sterols, anti-inflammatory agents, vasodilators, chemotherapeutic agents, and agents to treat infertility. Claim 55 is a dependent claim that depends from an allowable independent claim, and is thus allowable itself for the reasons stated above with respect to claim 54.

In view of the remarks set forth in this section, Applicants respectfully submit that claims 1, 4, 4, 7, 12, 22, 21, 26, 31, 32, 34, 50, 54, and 55 are in condition for allowance and respectfully request favorable consideration and the timely allowance of those claims.

2. Remarks on Paragraph 6 of the Office Action mailed on June 29, 2004: Rejection of Claims 20, 21, 23-25, 27, 39, and 40 as Obvious

In the Office Action mailed June 29, 2004, the Examiner rejects claims 20, 21, 23-25, 27, 39, and 40 as being unpatentable under 35 U.S.C. §103(a) over the Lucas application in view of U.S. Patent No. 6,086,909 to Harrison et al. ("the Harrison patent"). Applicants respectfully traverse the rejection.

In order to establish a *prima facie* case of obviousness, three basic criteria must be met: (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; (2) there must be a reasonable expectation of success; and (3) the prior art reference (or references when combined) must teach or suggest all the claim limitations. MPEP §2143. The Examiner bears the initial burden of establishing the *prima facie* case. See In re Piasecki, 223 U.S.P.Q. 785,787, 745 F.2d 1468, 1471 (Fed. Cir. 1984).

1. The Examiner has not met the burden of establishing prima facie obviousness by failing to identify the motivation in the Lucas application for modifying its teachings with the teachings of the Harrison patent.

Claim 20 is directed to the tampon of claim 1, wherein the therapeutic agent is substantially a liquid. Claim 21 is directed to the tampon of claim 1, wherein the therapeutic agent is an

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emulsion. Claim 23 is directed to the tampon of claim 1, wherein the therapeutic agent is a gel. Claim 24 is directed to the tampon of claim 1, wherein the therapeutic agent is an ointment. Claim 25 is directed to the tampon of claim 1, wherein the therapeutic agent is a salve. Claim 27 is directed to the tampon of claim 1, wherein the therapeutic agent is substantially a semi-solid. Claim 39 is directed to the tampon of claim 1, wherein the formulation including a therapeutic agent includes a foam component. Claim 40 is directed to the tampon of claim 1, wherein the formulation including a therapeutic agent includes a polymeric material. Neither of the two cited references (the Lucas application and the Harrison patent) disclose the claimed devices. The Examiner improperly "picked and chose" the components from the two references using the claimed invention as a template in order to form the rejection.

In the Office Action mailed June 29, 2004, the Examiner states "It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the various forms of the therapeutic agent of Lucas for the benefits disclosed in Harrison." In this Office Action, the Examiner attempts to provide an explanation of the motivation for combining the references. The Examiner's explanation is insufficient. The sole motivation asserted by the Examiner is one of gaining "the benefits disclosed in Harrison." It is unclear how reading the "benefits disclosed in Harrison" would motivate one to look to another reference. The "benefits disclosed in Harrison" purport to be gained by Harrison alone. There is also no motivation in the Lucas application to look beyond its four corners to gain any benefits. There is, therefore, no motivation within the patents to apply the teachings of one to the other. The Examiner does not adequately state why one of ordinary skill would read the Lucas application and then look to the Harrison patent to convert one device to the another device to arrive at the device of claims 20, 21, 23-25, 27, 39, and 40.

Further, the motivation to modify the prior art must flow from some teaching in the art that suggests the desirability or incentive to make the modification needed to arrive at the claimed invention. In re Napier, 55 F.3d 610, 613, 34 U.S.P.Q.2d 1782, 1784 (Fed. Cir. 1995). The Examiner has pointed to no disclosure within either patent that one of skill in the art would look to for such motivation or teaching. Again, the Examiner has not explained why one would look at device identified in the Lucas application and be motivated to change it by applying the teaching of the Harrison patent. The Examiner has failed to identify how the cited references suggest the desirability of modifying the device of the Lucas application to include components from the Harrison patent. In re Fritch, 972 F.2d 1260, 1266, 23 U.S.P.Q.2d 1780, 1783-84 (Fed. Cir. 1992) ("The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the

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modification."). Unless the Examiner provides an adequate explanation of the motivation to combine the cited references, it appears that she has used the claimed invention as a "template" to pick and choose the components of claims 20, 21, 23-25, 27, 39, and 40 from the prior art. Id. quoting In re Fine, 837 F.2d 1071, 1075, 5 U.S.P.Q.2d 1596, 1600 (Fed. Cir. 1988)¹. For at least these reasons, Applicants assert that a *prima facie* case of obviousness has not been made and that claims 20, 21, 23-25, 27, 39, and 40 are patentable over the references.

2. The Examiner has not met the burden of establishing prima facie obviousness by failing to meet the burden of establishing that the prior art reference (or references when combined) teach or suggest all the claim limitations. And by failing to meet the burden of establishing that there would be a reasonable expectation of success associated with modifying the device of the Lucas application to include components from the Harrison patent.

As discussed above with respect to claim 1, the Lucas application does not teach or suggest all of the claim limitations. Claim 1 as amended is directed to a tampon adapted to deliver a therapeutic agent, the tampon including absorbent material and a formulation including a therapeutic agent, wherein the therapeutic agent is a botanical, wherein the tampon has an outer layer, and wherein the outer layer includes a therapeutically sufficient amount of the botanical. As described in the Lucas application at page 3, lines 20-22, the "herbal preparation shall be evenly spread in a thin layer from the centre to the periphery of the herbal tampon following the concentric layers." As further illustrated in Figs. 1 and 2, the Lucas application discloses what might be analogized as a jelly roll model, wherein the layer of herbal preparation extends in a spiral manner from the center of the tampon to the periphery of the tampon. As stated in the Lucas application at page 3, lines 24-25, "Such layering of the herbal preparations shall give a slow release of the active constituents of the herbal preparations." Contrarily, the Applicants' claimed invention includes a therapeutically sufficient amount of botanical in an outer layer, and does so for at least the reason of enabling a quicker and more complete release of the botanical. In the device of the Lucas application, release of the active constituents competes with the in-rush of menstrual fluids. As a result, much of the active constituents will remain within the tampon. In addition, tampons are typically used for a limited time within the body; consequently, the "slow release" of the Lucas application will preclude complete release of its active constituents.

¹ "Here the Examiner relied upon hindsight to arrive at the determination of obviousness. It is impermissible to use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious. This court has previously stated that '[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.'"

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The Harrison patent does not correct these deficiencies because it does not teach or suggest a tampon adapted to deliver a therapeutic agent, the tampon including absorbent material and a formulation including a therapeutic agent, wherein the therapeutic agent is a botanical, wherein the tampon has an outer layer, and wherein the outer layer includes a therapeutically sufficient amount of the botanical. Nor does Harrison teach or suggest the subject matter of claims 20, 21, 23-25, 27, 39, and 40. The creams, ointments, etc. (Abstract and col. 13, lines 34-60) referenced by the Examiner are disclosed in the Harrison patent as acting alone with a drug. There is no teaching or suggestion in either reference as to why one would abandon the tampon of the Lucas application in favor of the creams, etc. of the Harrison patent, or why one would add a tampon to the independently-acting creams, etc. of the Harrison patent.

In addition to indicating why the cited references provide the requisite motivation and suggestion to be combined, the Examiner should also have indicated why the references provide the required expectation of succeeding in the endeavor. The Examiner has not shown that the references would have suggested to one of ordinary skill in the art that various components from the references should be combined and would have a reasonable likelihood of success. The Examiner has shown no motivation or expectation of success in combining a tampon with a drug-delivering cream, etc., each of which are purported to act adequately alone. Both the suggestion and the expectation of success must be found in the cited references, not in Appellants' disclosure. In re Dow Chemical, 837 F.2d 469, 473, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988).

In view of the remarks set forth in this section, Applicants respectfully submit that claims 20, 21, 23-25, 27, 39, and 40 are in condition for allowance and respectfully request favorable consideration and the timely allowance of those claims.

3. Remarks on Paragraph 7 of the Office Action mailed on June 29, 2004: Rejection of Claims 1, 3, 5, 28, 29, 35, 36, 38, 40, 47 and 49 as Obvious

In the Office Action mailed June 29, 2004, the Examiner rejects claims 1, 3, 5, 28, 29, 35, 36, 38, 40, 47 and 49 as being unpatentable under 35 U.S.C. §103(a) over U.S. Patent No. 3,490,454 to Goldfarb et al. ("the Goldfarb patent") in view of the Lucas application. Applicants respectfully traverse the rejection.

Again, in order to establish a *prima facie* case of obviousness, three basic criteria must be met: (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; (2) there must be a reasonable expectation of success; and (3) the prior art reference (or references when combined) must teach or suggest all the claim limitations.

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MPEP §2143. The Examiner bears the initial burden of establishing the *prima facie* case. See In re Piasecki, 223 U.S.P.Q. 785,787, 745 F.2d 1468, 1471 (Fed. Cir. 1984).

1. The Examiner has not met the burden of establishing prima facie obviousness by failing to identify the motivation in the Goldfarb patent for modifying its teachings with the teachings of the Lucas application.

Claim 1 is directed to a tampon adapted to deliver a therapeutic agent, the tampon comprising absorbent material and a formulation including a therapeutic agent, wherein the therapeutic agent is a botanical, wherein the tampon has an outer layer, and wherein the outer layer includes a therapeutically sufficient amount of the botanical. Claim 3 is directed to the tampon of claim 1, wherein the outer layer is a cover. Claim 5 is directed to the tampon of claim 4, wherein the liquid-permeable cover is a porous nonwoven sheet. Claim 28 is directed to the tampon of claim 1, wherein the therapeutic agent is encapsulated. Claim 29 is directed to the tampon of claim 1, further comprising an applicator, wherein pressure applied by the applicator to the tampon releases the formulation including the therapeutic agent. Claim 35 is directed to the tampon of claim 1, wherein the formulation including a therapeutic agent is applied to degradable fibers. Claim 36 is directed to the tampon of claim 1, wherein the absorbent material has an interstitial space, and wherein the formulation including a therapeutic agent is interspersed within the interstitial space. Claim 38 is directed to the tampon of claim 1, wherein the formulation including a therapeutic agent includes a hydrogel material. Claim 40 is directed to the tampon of claim 1, wherein the formulation including a therapeutic agent includes a polymeric material. Neither of the two cited references (the Lucas application and the Goldfarb patent) disclose the claimed devices. The Examiner improperly "picked and chose" the components from the two references using the claimed invention as a template in order to form the rejection.

In the Office Action mailed June 29, 2004, the Examiner states "It would have been obvious to modify the therapeutic agent of Goldfarb to include a botanical, since both Lucas and Goldfarb (col. 8, line 1) teach a bactericide and/or fungicide is desirable in the absorbent product." In this Office Action, the Examiner attempts to provide an explanation of the motivation for combining the references. The Examiner's explanation is insufficient. The sole motivation asserted by the Examiner, that "a bactericide and/or fungicide is desirable in the absorbent product," oversimplifies the teachings of each. The sole motivation in the Goldfarb patent is to address menstrual discharge once it is resident in a catamenial product: to obviate odors and to combat bacterial growth within such catamenial product (see col. 1, lines 66-69; col. 2, lines 13-16; col. 2, lines 34-42; col. 5, lines 30-35; among others). There is no substantive disclosure or teaching in the

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Goldfarb patent of treating the user of a catamenial product; consequently, the substances disclosed in the Goldfarb patent are not therapeutic agents. The substances disclosed in the Goldfarb patent are simply chemicals used to deodorize, de-color, or otherwise alter menstrual discharge. Because the Goldfarb patent discloses no therapeutic agents, there can be no motivation to search for alternate therapeutic agents. Further to this point, the Goldfarb patent does not interest itself in finding new substances, and, in fact, states that "Materials which perform these functions are well known in the art" (col. 8, lines 2-3). This does not motivate one to search for alternate substances, particularly ones that perform completely different functions, and more particularly ones that might be mentioned in a patent application 33 years later when perfectly suitable substances were known at the time the Goldfarb patent was filed. There is, therefore, no motivation within the patents to apply the teachings of one to the other. The Examiner does not adequately state why one of ordinary skill would read the Goldfarb patent and then look to the Lucas application to convert the device to the another device to arrive at the device and method of claims 1, 3, 5, 28, 29, 35, 36, 38, 40, 47 and 49.

Further, the motivation to modify the prior art must flow from some teaching in the art that suggests the desirability or incentive to make the modification needed to arrive at the claimed invention. In re Napier, 55 F.3d 610, 613, 34 U.S.P.Q.2d 1782, 1784 (Fed. Cir. 1995). The Examiner has pointed to no disclosure within either patent that one of skill in the art would look to for such motivation or teaching. Again, the Examiner has not explained why one would look at device identified in the Goldfarb patent and be motivated to change it by applying the teaching of the Lucas application. The Examiner has failed to identify how the cited reference suggests the desirability of modifying the device of the Goldfarb patent to include components from the Lucas application. In re Fritch, 972 F.2d 1260, 1266, 23 U.S.P.Q.2d 1780, 1783-84 (Fed. Cir. 1992) ("The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification."). Unless the Examiner provides an adequate explanation of the motivation to combine the cited references, it appears that she has used the claimed invention as a "template" to pick and choose the components of claims 1, 3, 5, 28, 29, 35, 36, 38, 40, 47 and 49 from the prior art. Id. quoting In re Fine, 837 F.2d 1071, 1075, 5 U.S.P.Q.2d 1596, 1600 (Fed. Cir. 1988)². For at

² "Here the Examiner relied upon hindsight to arrive at the determination of obviousness. It is impermissible to use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious. This court has previously stated that '[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.'"

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least these reasons, Applicants assert that a *prima facie* case of obviousness has not been made and that claims 1, 3, 5, 28, 29, 35, 36, 38, 40, 47 and 49 are patentable over the references.

2. The Examiner has not met the burden of establishing prima facie obviousness by failing to meet the burden of establishing that the prior art reference (or references when combined) teach or suggest all the claim limitations. And by failing to meet the burden of establishing that there would be a reasonable expectation of success associated with modifying the device of the Goldfarb patent to include components from the Lucas application.

As discussed above with respect to claims 1, 3, 5, 28, 29, 35, 36, 38, 40, 47 and 49, the Goldfarb patent does not teach or suggest all of the claim limitations. First, the device of the Goldfarb patent does not deliver a therapeutic agent, nor does it deliver anything at all. The substances in the Goldfarb patent are disclosed to treat menstrual discharge once such discharge is resident in a catamenial product. The Lucas application does not correct these deficiencies because substituting the grapefruit seed extract of the Lucas application for one of the substances in the Goldfarb patent would still only leave a catamenial product that attempts to alter menstrual discharge, yet delivers nothing. In addition to indicating why the cited references provide the requisite motivation and suggestion to be combined, the Examiner should also have indicated why the references provide the required expectation of succeeding in the endeavor. The Examiner has not shown that the references would have suggested to one of ordinary skill in the art that various components from the references should be combined and would have a reasonable likelihood of success. There is no motivation or suggestion that the device of the Goldfarb patent would be improved, or that a different product performing a different function would be successfully achieved. Both the suggestion and the expectation of success must be found in the cited references, not in Appellants' disclosure. In re Dow Chemical, 837 F.2d 469, 473, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988).

In view of the remarks set forth in this section, Applicants respectfully submit that claims 1, 3, 5, 28, 29, 35, 36, 38, 40, 47 and 49 are in condition for allowance and respectfully request favorable consideration and the timely allowance of those claims.

4. Remarks on Paragraph 8 of the Office Action mailed on June 29, 2004: Rejection of Claim 30 as Obvious

In the Office Action mailed June 29, 2004, the Examiner rejects claim 30 as being unpatentable under 35 U.S.C. §103(a) over the Lucas application in view of U.S. Patent No. 5,585,277 to Bowie et al. ("the Bowie patent"). Applicants respectfully traverse the rejection.

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In order to establish a *prima facie* case of obviousness, three basic criteria must be met: (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings; (2) there must be a reasonable expectation of success; and (3) the prior art reference (or references when combined) must teach or suggest all the claim limitations. MPEP §2143. The Examiner bears the initial burden of establishing the *prima facie* case. See In re Plasecki, 223 U.S.P.Q. 785,787, 745 F.2d 1468, 1471 (Fed. Cir. 1984).

1. The Examiner has not met the burden of establishing prima facie obviousness by failing to identify the motivation in the Lucas application for modifying its teachings with the teachings of the Bowie patent.

Claim 30 is directed to the tampon of claim 1, wherein the formulation includes a ligand adapted to target the therapeutic agent. Neither of the two cited references (the Lucas application and the Bowie patent) disclose the claimed devices. The Examiner Improperly "picked and chose" the components from the two references using the claimed invention as a template in order to form the rejection.

In the Office Action mailed June 29, 2004, the Examiner states "It would have been obvious to one having ordinary skill in the art to modify the therapeutic agent of Lucas with a ligand for the benefits disclosed in Bowie." In this Office Action, the Examiner attempts to provide an explanation of the motivation for combining the references. The Examiner's explanation is insufficient. The sole motivation asserted by the Examiner is one of gaining "the benefits disclosed in Bowie." It is unclear how reading the "benefits disclosed in Bowie" would motivate one to look to another reference. The "benefits disclosed in Bowie" purport to be gained by Bowie alone. There is also no motivation in the Lucas application to look beyond its four corners to gain any benefits. There is, therefore, no motivation within the patents to apply the teachings of one to the other. The Examiner does not adequately state why one of ordinary skill would read the Lucas application and then look to the Bowie patent to convert one device to the another device to arrive at the device of claim 30.

Further, the motivation to modify the prior art must flow from some teaching in the art that suggests the desirability or incentive to make the modification needed to arrive at the claimed invention. In re Napier, 55 F.3d 610, 613, 34 U.S.P.Q.2d 1782, 1784 (Fed. Cir. 1995). The Examiner has pointed to no disclosure within either patent that one of skill in the art would look to for such motivation or teaching. Again, the Examiner has not explained why one would look at device identified in the Lucas application and be motivated to change it by applying the teaching of

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the Bowie patent. The Examiner has failed to identify how the cited references suggest the desirability of modifying the device of the Lucas application to include components from the Bowie patent. In re Fritch, 972 F.2d 1260, 1266, 23 U.S.P.Q.2d 1780, 1783-84 (Fed. Cir. 1992) ("The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification."). Unless the Examiner provides an adequate explanation of the motivation to combine the cited references, it appears that she has used the claimed invention as a "template" to pick and choose the components of claim 30 from the prior art. Id. quoting In re Fine, 837 F.2d 1071, 1075, 5 U.S.P.Q.2d 1596, 1600 (Fed. Cir. 1988)³. For at least these reasons, Applicants assert that a *prima facie* case of obviousness has not been made and that claim 30 is patentable over the references.

2. The Examiner has not met the burden of establishing prima facie obviousness by failing to meet the burden of establishing that the prior art reference (or references when combined) teach or suggest all the claim limitations. And by failing to meet the burden of establishing that there would be a reasonable expectation of success associated with modifying the device of the Lucas application to include components from the Bowie patent.

As discussed above with respect to claim 1, the Lucas application does not teach or suggest all of the claim limitations. Claim 1 as amended is directed to a tampon adapted to deliver a therapeutic agent, the tampon including absorbent material and a formulation including a therapeutic agent, wherein the therapeutic agent is a botanical, wherein the tampon has an outer layer, and wherein the outer layer includes a therapeutically sufficient amount of the botanical. As described in the Lucas application at page 3, lines 20-22, the "herbal preparation shall be evenly spread in a thin layer from the centre to the periphery of the herbal tampon following the concentric layers." As further illustrated in Figs. 1 and 2, the Lucas application discloses what might be analogized as a jelly roll model, wherein the layer of herbal preparation extends in a spiral manner from the center of the tampon to the periphery of the tampon. As stated in the Lucas application at page 3, lines 24-25, "Such layering of the herbal preparations shall give a slow release of the active constituents of the herbal preparations." Contrarily, the Applicants' claimed invention includes a therapeutically sufficient amount of botanical in an outer layer, and does so for at least

³ "Here the Examiner relied upon hindsight to arrive at the determination of obviousness. It is impermissible to use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious. This court has previously stated that '[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.'"

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the reason of enabling a quicker and more complete release of the botanical. In the device of the Lucas application, release of the active constituents competes with the in-rush of menstrual fluids. As a result, much of the active constituents will remain within the tampon. In addition, tampons are typically used for a limited time within the body; consequently, the "slow release" of the Lucas application will preclude complete release of its active constituents.

The Bowie patent does not correct these deficiencies because it does not teach or suggest a tampon adapted to deliver a therapeutic agent, the tampon including absorbent material and a formulation including a therapeutic agent, wherein the therapeutic agent is a botanical, wherein the tampon has an outer layer, and wherein the outer layer includes a therapeutically sufficient amount of the botanical. Nor does Bowie teach or suggest the subject matter of claim 30. Bowie discloses a method for screening ligands for potential pharmaceutical effectiveness and thus does not disclose a formulation including a ligand adapted to target a therapeutic agent. There is no teaching or suggestion in either reference as to why one would add a screening method to the tampon of the Lucas application.

In addition to indicating why the cited references provide the requisite motivation and suggestion to be combined, the Examiner should also have indicated why the references provide the required expectation of succeeding in the endeavor. The Examiner has not shown that the references would have suggested to one of ordinary skill in the art that various components from the references should be combined and would have a reasonable likelihood of success. Both the suggestion and the expectation of success must be found in the cited references, not in Appellants' disclosure. In re Dow Chemical, 837 F.2d 469, 473, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988).

In view of the remarks set forth in this section, Applicants respectfully submit that claim 30 is in condition for allowance and respectfully request favorable consideration and the timely allowance of that claim.

5. Remarks on Paragraph 9 of the Office Action mailed on June 29, 2004: Rejection of Claims 6, 8, 9, 16, and 53 as Obvious

In the Office Action mailed June 29, 2004, the Examiner rejects claims 6, 8, 9, 16, and 53 as being unpatentable under 35 U.S.C. §103(a) over the Goldfarb patent in view of the Lucas application and further in view of U.S. Patent No. 4,726,976 to Karami et al. ("the Karami patent"). Applicants respectfully traverse the rejection.

In order to establish a *prima facie* case of obviousness, three basic criteria must be met: (1) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to

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combine reference teachings; (2) there must be a reasonable expectation of success; and (3) the prior art reference (or references when combined) must teach or suggest all the claim limitations. MPEP §2143. The Examiner bears the initial burden of establishing the *prima facie* case. See *In re Piasecki*, 223 U.S.P.Q. 785,787, 745 F.2d 1468, 1471 (Fed. Cir. 1984).

With respect to claims 6, 8, 9, and 16:

1. The Examiner has not met the burden of establishing *prima facie* obviousness by failing to identify the motivation in the Lucas application and the Goldfarb patent for modifying its teachings with the teachings of the Karami patent.

Claim 6 is directed to the tampon of claim 5, wherein the porous nonwoven sheet is a spunbond web formed from polypropylene or polyethylene fibers or a mixture thereof. Claim 8 is directed to the tampon of claim 5, wherein the porous nonwoven sheet is formed from fibers of hydrophobic polymer. Claim 9 is directed to the tampon of claim 8, wherein the botanical is coated on the fibers. Claim 16 is directed to the tampon of claim 1, further comprising non-absorbent material.

In the Office Action mailed June 29, 2004, the Examiner states "It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Goldfarb with a hydrophobic cover layer for the benefits disclosed in Karami." In this Office Action, the Examiner attempts to provide an explanation of the motivation for combining the references. The Examiner's explanation is insufficient. The sole motivation asserted by the Examiner is one of gaining "the benefits disclosed in Karami." It is unclear how reading the "benefits disclosed in Karami" would motivate one to look to another reference. The "benefits disclosed in Karami" purport to be gained by Karami alone. There is also no motivation in the Goldfarb patent to look beyond its four corners to gain any benefits. There is, therefore, no motivation within the patents to apply the teachings of one to the other. The Examiner does not adequately state why one of ordinary skill would read the Goldfarb patent and then look to the Karami patent to convert one device to the another device to arrive at the device of claims 6, 8, 9, and 16.

Further, the motivation to modify the prior art must flow from some teaching in the art that suggests the desirability or incentive to make the modification needed to arrive at the claimed invention. In re Napier, 55 F.3d 610, 613, 34 U.S.P.Q.2d 1782, 1784 (Fed. Cir. 1995). The Examiner has pointed to no disclosure within either patent that one of skill in the art would look to for such motivation or teaching. Again, the Examiner has not explained why one would look at device identified in the Goldfarb patent and be motivated to change it by applying the teaching of the Karami patent. The Examiner has failed to identify how the cited references suggest the

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desirability of modifying the device of the Goldfarb patent to include components from the Karami patent. In re Fritch, 972 F.2d 1260, 1266, 23 U.S.P.Q.2d 1780, 1783-84 (Fed. Cir. 1992) ("The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification."). Unless the Examiner provides an adequate explanation of the motivation to combine the cited references, it appears that she has used the claimed invention as a "template" to pick and choose the components of claims 6, 8, 9, and 16 from the prior art. Id. quoting In re Fine, 837 F.2d 1071, 1075, 5 U.S.P.Q.2d 1596, 1600 (Fed. Cir. 1988)⁴. For at least these reasons, Applicants assert that a *prima facie* case of obviousness has not been made and that claims 6, 8, 9, and 16 are patentable over the references.

2. The Examiner has not met the burden of establishing prima facie obviousness by failing to meet the burden of establishing that the prior art reference (or references when combined) teach or suggest all the claim limitations. And by failing to meet the burden of establishing that there would be a reasonable expectation of success associated with modifying the device of the Lucas application to include components from the Goldfarb and Karami patents.

As discussed above with respect to claim 1, the Lucas application does not teach or suggest all of the claim limitations. Claim 1 as amended is directed to a tampon adapted to deliver a therapeutic agent, the tampon including absorbent material and a formulation including a therapeutic agent, wherein the therapeutic agent is a botanical, wherein the tampon has an outer layer, and wherein the outer layer includes a therapeutically sufficient amount of the botanical. As described in the Lucas application at page 3, lines 20-22, the "herbal preparation shall be evenly spread in a thin layer from the centre to the periphery of the herbal tampon following the concentric layers." As further illustrated in Figs. 1 and 2, the Lucas application discloses what might be analogized as a jelly roll model, wherein the layer of herbal preparation extends in a spiral manner from the center of the tampon to the periphery of the tampon. As stated in the Lucas application at page 3, lines 24-25, "Such layering of the herbal preparations shall give a slow release of the active constituents of the herbal preparations." Contrarily, the Applicants' claimed invention includes a therapeutically sufficient amount of botanical in an outer layer, and does so for at least the reason of enabling a quicker and more complete release of the botanical. In the device of the

⁴ "Here the Examiner relied upon hindsight to arrive at the determination of obviousness. It is impermissible to use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious. This court has previously stated that '[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.'"

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Lucas application, release of the active constituents competes with the in-rush of menstrual fluids. As a result, much of the active constituents will remain within the tampon. In addition, tampons are typically used for a limited time within the body; consequently, the "slow release" of the Lucas application will preclude complete release of its active constituents.

The Goldfarb patent does not correct these deficiencies because it does not teach or suggest a tampon adapted to deliver a therapeutic agent, the tampon including absorbent material and a formulation including a therapeutic agent, wherein the therapeutic agent is a botanical, wherein the tampon has an outer layer, and wherein the outer layer includes a therapeutically sufficient amount of the botanical. Nor does Goldfarb teach or suggest the subject matter of claims 6, 8, 9, or 16.

In addition, the Karami patent does not correct these deficiencies. The Karami patent does not address the structure of a tampon, and thus cannot correct the structural deficiencies of the Lucas application. There is no teaching or suggestion in any of the references as to why one would add a different material from the Karami patent.

In addition to indicating why the cited references provide the requisite motivation and suggestion to be combined, the Examiner should also have indicated why the references provide the required expectation of succeeding in the endeavor. The Examiner has not shown that the references would have suggested to one of ordinary skill in the art that various components from the references should be combined and would have a reasonable likelihood of success. Both the suggestion and the expectation of success must be found in the cited references, not in Appellants' disclosure. In re Dow Chemical, 837 F.2d 469, 473, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988).

With respect to claim 53:

1. The Examiner has not met the burden of establishing prima facie obviousness by failing to identify the motivation in the Goldfarb patent and the Lucas application for modifying its teachings with the teachings of the Karami patent.

Claim 53 is directed to a method of producing a tampon adapted to deliver a therapeutic agent, the method including treating a porous nonwoven sheet formed from hydrophobic polymer with a formulation including a therapeutic agent, wherein the therapeutic agent is a botanical; and forming the tampon so as to include absorbent material, such that the sheet at least partially covers the tampon. None of the three cited references (the Lucas application, the Goldfarb patent, and the Karami patent) disclose the claimed devices. The Examiner improperly "picked and chose" the components from the three references using the claimed invention as a template in order to form the rejection.

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In the Office Action mailed June 29, 2004, the Examiner states "It would have been obvious to modify the therapeutic agent of Goldfarb to include a botanical, since both Lucas and Goldfarb (col. 8, line 1) teach a bactericide and/or fungicide is desirable in the absorbent product." The insufficiency of this position is discussed above on page 17. The Examiner also states "It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Goldfarb with a hydrophobic cover layer for the benefits disclosed in Karami." Similarly, the insufficiency of this position is discussed above on page 23. There is, therefore, no motivation within the patents to apply the teachings of one to the others. The Examiner does not adequately state why one of ordinary skill would read one of these patents and then look to the other two patents to convert one device to the another device to arrive at the device of claim 53.

Further, the motivation to modify the prior art must flow from some teaching in the art that suggests the desirability or incentive to make the modification needed to arrive at the claimed invention. In re Napier, 55 F.3d 610, 613, 34 U.S.P.Q.2d 1782, 1784 (Fed. Cir. 1995). The Examiner has pointed to no disclosure within either patent that one of skill in the art would look to for such motivation or teaching. Again, the Examiner has not explained why one would look at device identified in one of these patents and be motivated to change it by applying the teaching of the other two patents. The Examiner has failed to identify how the cited references suggest the desirability of modifying the device of one of the patents to include components from the other two patents. In re Fritch, 972 F.2d 1260, 1266, 23 U.S.P.Q.2d 1780, 1783-84 (Fed. Cir. 1992) ("The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification."). Unless the Examiner provides an adequate explanation of the motivation to combine the cited references, it appears that she has used the claimed invention as a "template" to pick and choose the components of claim 53 from the prior art. Id. quoting In re Fine, 837 F.2d 1071, 1075, 5 U.S.P.Q.2d 1596, 1600 (Fed. Cir. 1988)⁵. For at least these reasons, Applicants assert that a *prima facie* case of obviousness has not been made and that claim 53 is patentable over the references.

2. The Examiner has not met the burden of establishing prima facie obviousness by failing to meet the burden of establishing that the prior art reference (or references when combined) teach or

⁵ "Here the Examiner relied upon hindsight to arrive at the determination of obviousness. It is impermissible to use the claimed invention as an instruction manual or 'template' to piece together the teachings of the prior art so that the claimed invention is rendered obvious. This court has previously stated that '[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.'"

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suggest all the claim limitations. And by failing to meet the burden of establishing that there would be a reasonable expectation of success associated with modifying the device of the Lucas application to include components from the Goldfarb and Karami patents.

There is no teaching or suggestion in either reference as to why one would add a screening method to the tampon of the Lucas application.

In addition to indicating why the cited references provide the requisite motivation and suggestion to be combined, the Examiner should also have indicated why the references provide the required expectation of succeeding in the endeavor. The Examiner has not shown that the references would have suggested to one of ordinary skill in the art that various components from the references should be combined and would have a reasonable likelihood of success. Both the suggestion and the expectation of success must be found in the cited references, not in Appellants' disclosure. In re Dow Chemical, 837 F.2d 469, 473, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988).

In view of the remarks set forth in this section, Applicants respectfully submit that claims 6, 8, 9, 16, and 53 are in condition for allowance and respectfully request favorable consideration and the timely allowance of those claims.

In conclusion, and in view of the remarks set forth above, Applicants respectfully submit that the application and the claims are in condition for allowance and respectfully request favorable consideration and the timely allowance of pending claims 1, 3-41, 46-50, and 52-56. If any additional information is required, the Examiner is invited to contact the undersigned at (920) 721-8863.

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The Commissioner is hereby authorized to charge any prosecutorial fees (or credit any overpayment) associated with this communication to Kimberly-Clark Worldwide, Inc. deposit account number 11-0875. If a fee is required for an extension of time under 37 C.F.R. 1.136 not accounted for above, such extension is requested and should also be charged to our Deposit Account.

Respectfully submitted,

KIMBERLY M. GEISER, ET AL.

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CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this correspondence is being facsimile transmitted to the United State Patent and Trademark Office Fax No. (703) 872-9306 on November 16, 2004.

By: 

Mary L. Roberts